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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,663	12/09/2003	Anurag K. Singh	60005161-0060	6362

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SONNENSCHN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

EXAMINER

HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/731,663

Applicant(s)

SINGH, ANURAG K.

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 10-14, 18-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>15 Jan 2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. The Examiner acknowledges the addition of claim 22 as well as the cancellation of claim 21. Claims 10-14, 18-20 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on 28 February 2007.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6, 8 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Andrea (U.S. Patent No. 5,720,717). D'Andrea discloses an apparatus for applying radiation therapy to a body cavity accessible through an existing orifice. Regarding claims 1, 2 and 4, D'Andrea teaches a balloon **120** (see Fig. 3) adapted to be inflated with a fluid (col. 2, lines 47-52) through conduit **164**. A catheter **150** extends over a portion of the balloon (see Fig. 3 and col. 5, lines 49-54). The catheter may further run along an interior surface of the balloon, (see Fig. 6 and col. 6, lines 51-56) which is in communication with conduit **164**. Regarding claims 3 and 8, a radiotherapeutic rod **50** of the apparatus is loaded with pellets, seeds, wires or other

such sources of radiation (col. 4, lines 39-42). Once the radiation sources have been loaded into the device and the apparatus inserted within the patient, the balloon **120** is inflated to move the rods having the radiation sources, closer to the diseased tissue (col. 4, lines 51-57).

In view of claim 6, a secondary balloon **30**, adjacent the first balloon, is connected to a second conduit **160**, which aids as a channel for fluid entry and subsequent inflation of the secondary balloon (col. 5, lines 56-61).

Regarding claim 15, the radiation receiving member or "catheter" is secured to the balloon. Following such, the balloon and catheter assembly may be inserted through the body orifice. A radiation source or radiotherapeutic rod, is inserted into the "catheter" such that it is adjacent the balloon. The balloon is then inflated to move the rods closer to the cavity or vessel wall and radiation therapy of the diseased tissues is commenced for a prescribed duration (col. 4, lines 39-57). Referring to claim 16, since the balloon taught by D'Andrea is permitted for use in various body cavities, it is noted that slight adjustments to the balloon will be made in order to accommodate the specific lumen of interest. Furthermore, D'Andrea teaches that the inflated balloon also may be moved, pushed, repositioned and otherwise manipulated during the tissue therapy (col. 1, lines 19-27), thus it is interpreted to rotate within the cavity in accordance with claim 16.

In view of claim 17, a second balloon **30**, adjacent to a first balloon **120** also has a deflated state in which the second balloon **30** is also adapted for inflation and insertion into the cavity of a patient. The balloons are inserted simultaneously, and the second

balloon is inflated by means of an inflation tube until the point at which adequate securement of the device within the orifice is determined and its position maintained (col. 5, lines 57-67 - col. 6, lines 1-8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Andrea (U.S. Patent No. 5,720,717) in view of Beyer et al. (U.S. Patent No. 5,354,293).

D'Andrea discloses the invention as claimed, see rejection supra; however D'Andrea fails to disclose a conduit which is at least partially transparent. Beyer et al. (hereinafter Beyer) teaches an apparatus for irradiating the walls of a cavity within a patient.

Regarding claim 5, Beyer teaches a transparent conduit **1**, disposed within an organ of a patient (col. 2, lines 35-38). The apparatus further includes a transparent positioning balloon (col. 4, lines 6-17), as taught by D'Andrea and the instant specification. Such an apparatus is used for the illumination of the walls of cavities of a patient's organs (col. 1, lines 14-17). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have modified a conduit within a radiation apparatus as taught by D'Andrea to be transparent as suggested by Beyer in order to

provide a radiation apparatus that enables accurate placement and distribution of radiation by increasing the surgeon's visibility of the internal structures.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Andrea (U.S. Patent No. 5,720,717). D'Andrea discloses a system for treating a lumen of a body comprising two balloons, **120, 30**. D'Andrea does not expressly disclose the second balloon surrounding the first balloon. Instead, D'Andrea discloses an apparatus whereby the second balloon is adjacent the first balloon. As in the invention of the instant application, D'Andrea discloses a second balloon for the purpose of positioning the inflatable system within a particular cavity according to its dimensions. Accordingly, the secondary balloon of D'Andrea may be placed adjacent the first balloon for accurate positioning as also taught in the instant application (see Fig. 10 and 11 of D'Andrea). Furthermore, the balloons of both D'Andrea, also introduced in a deflated state and subsequently inflated following insertion, and the instant application, are sized and shaped for use within a particular cavity (col.3, lines 8-18 of D'Andrea and [0030] of the instant application).

Applicant has not disclosed that having the secondary balloon surrounding the first balloon solves any stated problem or is used for any particular purpose other than its adaption for insertion into a particular cavity, as also suggested by D'Andrea. Moreover, it appears that the secondary balloon of D'Andrea and applicant's invention would perform equally well with the secondary balloon surrounding the first balloon.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified D'Andrea such that the second

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balloon surrounds the first balloon because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the D'Andrea since both the second balloon of D'Andrea and the second balloon of the instant application act to aid placement of the treatment device within a particular cavity.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Andrea (U.S. Patent No. 5,720,717) in view of Campbell et al. (U.S. Patent No. 5,409,483).

D'Andrea discloses the invention as claimed, see rejection supra; however D'Andrea fails to disclose a transparent balloon with a viewing apparatus for viewing the general area. Campbell et al. (hereinafter Campbell) teach a device for treating afflictions and diseases associated with lumens of the body. Regarding claim 9, Campbell teaches a multi-lumen catheter having a transparent balloon and a direct visualization scope positioned within a lumen of the catheter for viewing tissues on the wall of the urethra against the balloon clearly and consistently by the surgeon (col. 3, lines 28-37 and col. 7, lines 51-53). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have modified a catheter and balloon assembly for insertion into an orifice as disclosed by D'Andrea, to incorporate an element of transparency and visualization as suggested by Campbell, for increased viewing and positioning of the apparatus within a lumen of a patient prior to treatment.

Conclusion

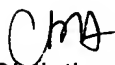
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pub. No. 2005/0101823 to Linares et al. discloses a treatment device for accurate positioning within a cavity of a patient requiring radiation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Christine D Hopkins
Examiner
Art Unit 3735

Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735